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Mats Inganas

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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER

HURST, JONATHAN M

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,182	Applicant(s) INGANAS, MATS	
	Examiner JONATHAN M. HURST	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/21/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/26/2006 and 02/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 9-11 are objected to because of the following informalities:

Claim 9 recites the limitation "said volume-metering unit" which is not recited prior to said limitation. Appropriate correction is required.

Claim 10 recites the limitations "said volume-metering unit" and "said group(s)" which is not recited prior to said limitation. Appropriate correction is required.

Claim 11 recites the limitation "said volume-metering unit" which is not recited prior to said limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, and 3-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mian et al. (US 6,319,469)

Regarding claims 1 and 4 Mian et al. discloses a collection of one or more microfluidic devices which together carry a plurality of microchannel structures each of which comprises a reaction microcavity in which there is a solid phase with an immobilized affinity ligand L, wherein: (See Fig. 1A, Fig. 1C, Fig. 17L,3 and Col. 43 Lines 25-40)

(i) the plurality comprises two or more different sets of microchannel structures, and (See Fig. 17L where each disk layer comprises a set of different channels Fig. 17A where disk contains sets of different channels and Col. 33 Lines 33-36 where a device performs a set of procedures or multiple embodiments of the same procedure)

(ii) the affinity ligand L is directed to the same counterpart (binder, B) independent of set, and (See Col. 33 Lines 33-36 where sets of the same procedure are performed)

(iii) the sets differ with respect to

a) the capacity for binder B per reaction microcavity and/or the capacity

per unit volume of the solid phase in a reaction microcavity, and/or (See Col. 8 Lines 30-35 where reservoirs act as microcavity and sizes differ depending upon embodiment and thus have different capacities for reagents)

b) the base matrix of the solid phase between the sets but are equal within each set. (See Fig. 17L where base is different for each set of channels)

Regarding claim 3 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein wherein at least one of said devices comprises

a) at least two of said sets of microchannel structures, and/or

b) only one set of microchannel structures, with the proviso that the collection comprises two or more devices which are different with respect to the kind of sets they carry.

(See Fig. 17L where device contains more than one layer and set of microchannel structures).

Regarding limitations recited in claim 4 which are directed to a manner of operating disclosed collection, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim.

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Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding claim 5 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein L is selected amongst biotin-binding compounds and streptavidin-binding compounds, respectively, or vice versa. (See Col 43 Lines 30-37 biotin binding streptavidin is used).

Regarding claim 6 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein L has two or more binding sites for B. (See Col 43 Lines 30-37 biotin binding streptavidin is used and it is inherent that streptavidin has more than one binding site for biotin).

Regarding claim 7 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein

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(a) that each set on a device is grouped into one or more groups of fluidly equivalent microchannel structures, and (See Fig. 17L where sets on each layer are groups of fluidly equivalent microchannel structures)

(b) that each group is located to a particular subarea of the device. (See Fig. 17L where each layer is a subarea of the device and contains a group)

Regarding claim 8 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said reaction microcavity in at least one, preferably all, of said microchannel structures in the upstream direction is connected to a volume-metering unit. (See Fig. 13B and Col. 26 Lines 15-24)

Regarding claim 9 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said volume-metering unit is part of an inlet arrangement for liquid. (See Fig. 13B and Col. 26 Lines 15-24)

Regarding claim 10 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said volume-metering unit within at least one of said group(s) are part of a distribution manifold for distributing liquid to the reaction

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microcavities of the group, with the proviso that each of said at least one group comprises two or more microchannel structures. (See Fig. 13B and Col. 26 Lines 15-24 where multiple samples are dispensed to a group of microchannels)

Regarding claim 11 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein the inner wall of each of said volume-metering units have a sufficient hydrophilicity for said unit to filled by capillarity once an aqueous liquid have entered the unit, and b) a valve at its outlet end, for instance a passive valve. (See Col. 26 Lines 15-24 where volume metering units have appropriate specific surface properties and Col. 14 Lines 45-55 where hydrophilicity is a surface property and Col. 17 Lines 38-41 where fluid movement is controlled by valves)

Regarding claim 12 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein at least one of the solute S and its affinity counterpart ACs, and/or at least one of the binder B and the ligand L comprise a structure selected from the group_of amongst peptide structure consisting of including poly/oligo-peptide and protein structure, carbohydrate structure, lipid structure including steroid structure, nucleotide structure including nucleic acid structure, and polymeric structure. (See Col. 43 Lines 30-34)

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Regarding limitations recited in claim 12 which are directed to a manner of operating disclosed collection, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 6,319,469) as applied to claims 1, and 3-12 above.

Regarding claim 2, Mian et al. discloses all of the claim limitations as set forth above, but the reference does not explicitly disclose the collection wherein at least one of the sets of the collection have a binding capacity difference with a factor ≥ 1.2 compared to the binding capacity for the set having the lowest binding capacity. Altering the binding capacities in different sets of microchannels/microcavities allows for more specific reaction and analysis of a wide range of sample types and concentrations and the precise binding capacity differences would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed binding capacity difference factor cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the binding capacity difference factor in the apparatus of Mian et al. to obtain the desired analytic and reactive capabilities of the device. (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

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7. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 6,319,469) as applied to claims 1-12 above in view of Jacobs et al. (US 2002/0095073)

Regarding claims 13 and 14 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said solid phase is in a dry state (See Col. 39 Line 65- Col. 40 Line 2 where disk is dried) but does not disclose the collection comprising in addition to the solid phase one or more bed preserving agents or wherein at least one of said one or more bed-preserving agents is a microcavity adherence agent.

Jacobs et al. describes the use of a bed preserving agents wherein bed-preserving agents is a microcavity adherence agent. (See [0019] where cross-linked straptavidin is immobilized as a preserving agent)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the bed preserving agent of Jacobs in the collection of Main because doing so helps preserve and stabilize the biological activity of the device. (See Jacobs [0019])

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/

Primary Examiner, Art Unit 1797

/J. M. H./

Examiner, Art Unit 1797